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110TH CONGRESS
1ST SESSION

H. R. 194

To amend the Internal Revenue Code of 1986 with respect to the purchase of prescription drugs by individuals who have attained retirement age, and to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs and the sale of such drugs through Internet sites.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 4, 2007

Mr. PAUL introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Internal Revenue Code of 1986 with respect to the purchase of prescription drugs by individuals who have attained retirement age, and to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs and the sale of such drugs through Internet sites.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug Affordability Act''.

TITLE I—AMENDMENTS TO INTERNAL REVENUE CODE OF 1986

SEC. 101. INCOME TAX CREDIT FOR PRESCRIPTION DRUGS PURCHASED BY INDIVIDUALS WHO HAVE ATTAINED RETIREMENT AGE.

(a) IN GENERAL.—Subpart A of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to nonrefundable personal credits) is amended by inserting after section 25D the following new section:

''SEC. 25E. PRESCRIPTION DRUGS PURCHASED BY INDIVIDUALS WHO HAVE ATTAINED SOCIAL SECURITY RETIREMENT AGE.

''(a) IN GENERAL.—In the case of an individual who has attained social security retirement age, there shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to 80 percent of the amount paid by the taxpayer during the taxable year (and not compensated for by insurance or otherwise) for any prescribed drug (as defined in section 213(d)(3)) for use by such individual.

''(b) SOCIAL SECURITY RETIREMENT AGE.—For purposes of this section, the term 'social security retirement age' means retirement age (as defined in section 216(l)(1) of the Social Security Act).

''(c) DENIAL OF DOUBLE BENEFIT.—

''(1) COORDINATION WITH MEDICAL EXPENSE DEDUCTION.—The amount which would (but for this subsection) be taken into account by the taxpayer under section 213 for the taxable year shall be reduced by the credit (if any) allowed by this section to the taxpayer for such year.

''(2) COORDINATION WITH MEDICAL AND HEALTH SAVINGS ACCOUNTS.—No credit shall be allowed under this section for amounts paid from any Archer MSA (as defined in section 220(d)) or any health savings account (as defined in section 223(d)).

''(d) ELECTION NOT TO HAVE CREDIT APPLY.—This section shall not apply to a taxpayer for a taxable year if the taxpayer elects not to have this section apply for such year.''.

(b) CLERICAL AMENDMENT.—The table of sections for subpart A of part IV of subchapter A of chapter 1 of such Code is amended by inserting after the item relating to section 25D the following new item:

''Sec. 25E. Prescription drugs purchased by individuals who have attained social security retirement age.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning more than 1 year after the date of the enactment of this Act.

TITLE II—AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

SEC. 201. FACILITATION OF IMPORTATION OF DRUGS APPROVED BY FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) by striking section 804; and

(2) in section 801(d)—

(A) by striking paragraph (2); and

(B) by striking ''(d)(1)'' and all that follows through the end of paragraph (1) and inserting the following:

''(d)(1)(A) A person who meets applicable legal requirements to be an importer of drugs described in subparagraph (B) may import such a drug (without regard to whether the person is a manufacturer of the drug) if the person submits to the Secretary an application to import the drug and the Secretary approves the application.

''(B) For purposes of subparagraph (A), the drugs described in this subparagraph are drugs that are subject to section 503(b)(1) or that are composed wholly or partly of insulin.

''(C) The Secretary shall approve an application under subparagraph (A) if the application demonstrates that the drug to be imported meets all requirements under this Act for the admission of the drug into the United States, including demonstrating that—

''(i) an application for the drug has been approved under section 505, or as applicable, under section 351 of the Public Health Service Act; and

''(ii) the drug is not adulterated or misbranded.

''(D) Not later than 60 days after the date on which an application under subparagraph (A) is submitted to the Secretary, the Secretary shall—

''(i) approve the application; or

''(ii) refuse to approve the application and provide to the person who submitted the application the reason for such refusal.

''(E) This paragraph may not be construed as affecting any right secured by patent.''.

(b) CONFORMING AMENDMENTS.—Section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended—

(1) by redesignating paragraphs (3) and (4) as paragraphs (2) and (3), respectively;

(2) in subclause (III) of paragraph (2)(A)(i) (as redesignated by this subsection), by striking ''paragraph (4)'' and inserting ''paragraph (3)''; and

(3) in paragraph (3) (as redesignated by this subsection), by striking ''paragraph (3)'' each place such term appears and inserting ''paragraph (2)''.

SEC. 202. INTERNET SALES OF PRESCRIPTION DRUGS.

Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) is amended by adding at the end the following paragraph:

''(6)(A) With respect to the interstate sale of a prescription drug through an Internet site, the Secretary may not with respect to such sale take any action under this Act against any of the persons involved if—

''(i) the sale was made in compliance with this Act and with State laws that are applicable to the sale of the drug; and

''(ii) accurate information regarding compliance with this Act and such State laws is posted on the Internet site.

''(B) For purposes of subparagraph (A), the sale of a prescription drug by a person shall be considered to be an interstate sale of the drug through an Internet site if—

''(i) the purchaser of the drug submits the purchase order for the drug, or conducts any other part of the sales transaction for the drug, through an Internet site; and

''(ii) pursuant to such sale, the person introduces the drug into interstate commerce or delivers the drug for introduction into such commerce.

''(C) Subparagraph (A) may not be construed as authorizing the Secretary to enforce any violation of State law.

''(D) For purposes of this paragraph, the term 'prescription drug' means a drug that is subject to paragraph (1).''.

SEC. 203. REGULATIONS OF SECRETARY OF HEALTH AND HUMAN SERVICES; EFFECTIVE DATE.

(a) REGULATIONS.—Before the expiration of the period specified in subsection (b), the Secretary of Health and Human Services shall promulgate regulations to carry out the amendments to the Federal Food, Drug, and Cosmetic Act that are made by sections 201 and 202.

(b) EFFECTIVE DATE.—The amendments to the Federal Food, Drug, and Cosmetic Act that are made by sections 201 and 202 take effect upon the expiration of the one-year period beginning on the date of the enactment

of this Act, without regard to whether the regulations required in subsection (a) have been promulgated.

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